

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

COOK INCORPORATED,)	
)	
Plaintiff,)	
)	
v.)	Case No. 1:09-cv-1248-TWP-DKL
)	
ENDOLOGIX, INC.,)	
)	
Defendant.)	

ENTRY ON CLAIM CONSTRUCTION

This patent infringement case involves two patents that relate to endovascular technologies. The Court has been called upon to construe disputed claims, terms, phrases, and clauses of U.S. Patent No. 5,035,706 (the “‘706 patent”) and U.S. Patent No. 5,755,777 (the “‘777 patent”) pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996). The Plaintiff in this case is Cook Incorporated (“Cook”), the owner of the ‘706 and ‘777 patents. The Defendant in this case is Endologix, Inc. (“Endologix”). On April 15, 2011, the Court held oral arguments on claim construction. The parties have submitted thorough and well-crafted briefs and supplementary materials to the Court, and jurisdiction is proper under 28 U.S.C. § 1338.

BACKGROUND

A. Type of devices

This patent dispute involves medical devices that treat abdominal aortic aneurysms (“AAA”). An AAA is caused by a weakening of the wall of the aorta, the largest human artery.

This weakening can cause a balloon-like enlargement to develop in the aorta, increasing the chances of a rupture. Aortic ruptures are often fatal.

To understand how these lifesaving devices generally work, some brief background is instructive. Until the 1990's, AAA's were typically treated through surgery that was incredibly risky and painful. The surgeon had to open the patient's chest and/or abdomen; move the patient's intestines to expose the aorta; cut out the diseased portion of the patient's aorta; and sew a new graft conduit into the aorta while diverting blood flow to the patient's lower body. Given the invasive and traumatic nature of this procedure, the patient faced a long and uncertain recovery.

Thankfully, brilliant innovators pushed technology forward. Eventually, surgeons began using self-expanding stent grafts, or small tubular wire cages (i.e. stents) covered with fabric grafts (i.e. grafts), to treat AAA's. These stent-based procedures obviate the need to cut open the patient's chest and/or abdomen, move intestines, and interrupt blood flow to the lower body. In turn, these stent-based procedures are far less risky and invasive, requiring shorter hospital stays and less recovery time.

Generally, to effectuate these procedures, the surgeon inserts a tube containing an expandable stent graft into the patient through a small incision, usually in the groin to give access to the femoral artery. The tube carries the stent, in a compressed state, to the treatment site. Once there, the stent is released and it self-expands into position. Upon expanding, the stent serves as a new pathway for blood flow down the aorta, relieving pressure on the AAA and thus preventing a rupture.

B. Parties and products

Numerous companies make stents, including Cook and Endologix. Cook's flagship stent is called the Zenith (which is not at issue). Endologix's is called the PowerLink (which is allegedly infringing a Cook patent). Cook alleges that Endologix, through the sale of its PowerLink stent and accompanying delivery system (the "Intuitrak"), is infringing two Cook patents: (1) the '706 patent, which relates to the actual stent; and (2) the '777 patent, which relates to the delivery system that carries the stent to the treatment site. The Court will discuss these patents in more detail in the discussion section below.

LEGAL STANDARD

In order to win a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman*, 517 U.S. at 374 (citation and internal quotations omitted). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the words of the patent's claims. *Johnson Worldwide Associates, Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed.Cir.1999). Patent claims are construed as a matter of law. *Markman*, 52 F.3d at 979. The Federal Circuit has emphasized that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (citation and internal quotations omitted).

The words of a claim are generally given their "ordinary and customary meaning," as understood by a person of skill in the art at the time the patent was filed. *Id.* at 1312-13. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316 (citation and internal quotations omitted). "[A]bsent contravening evidence from the specification or

prosecution history, plain and unambiguous claim language controls the construction analysis.” *DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1347 (Fed. Cir. 2008).

In the process of discerning the meaning of a claim as understood by a person of ordinary skill in the art, a court may look to various sources. Most notably, courts may turn to intrinsic evidence, which includes “the words of the claims themselves, the remainder of the specification, [and] the prosecution history.” *Phillips*, 415 F.3d at 1314. The Federal Circuit has recognized that the patent specification is “the single best guide to the meaning of a disputed term.” *Id.* at 1315 (citation and internal quotations omitted). Courts may also consult the written history of the patentee’s dealings with the Patent and Trademark Office (“PTO”) (i.e. the prosecution history) because it provides insight into how the PTO and the inventor understood the invention. *Id.* at 1317. Finally, courts may consider evidence external to the patent (i.e. extrinsic evidence) – such as expert testimony, treatises, or dictionaries – but this evidence is less significant than intrinsic evidence. *Id.*

Specific examples (i.e. “preferred embodiments”) in the written description of the patent can shed light on the intended scope of the claims. *Boss Control, Inc. v. Bombardier Inc.*, 410 F.3d 1372, 1377 (Fed. Cir. 2005) (citations and internal quotations omitted). Nonetheless, “[t]he patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.” *Kara Technology Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1347-48 (Fed. Cir. 2009). In that same vein, “[t]he law does not require...that an applicant describe in his specification every conceivable and possible future embodiment of his invention.” *SRI Int’l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (*en banc*).

DISCUSSION

The discussion section is divided into two parts. First, the Court will discuss the background of the '706 patent, the relevant claims, and then resolve the disputed terms. Then, the Court will do the same for the '777 patent.

A. The '706 patent

Cook has stood at the forefront of endovascular technology for numerous decades. Significantly, Cook's '706 patent claims an improvement on an earlier Cook patent, U.S. Patent No. 4,580,568 ("the '568 patent"). The '568 patent (which expired in 2004 and was not asserted in this case) covers a specific type of self-expanding stent known as a Z-stent, which is made from a single wire bent into a "zig-zag" shape. A depiction of a Z-stent is set forth below.

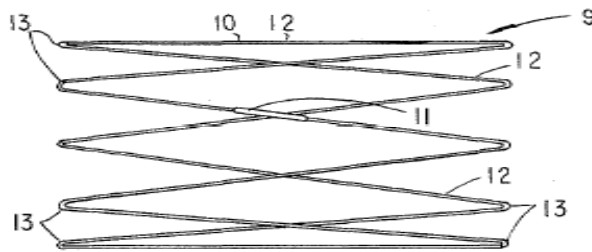


Fig. 1

Z-stents can be compressed, inserted into a vessel, and then re-expanded by virtue of the spring-expanding nature of their wire. This self-expanding stent technology was, in Cook's words, "wildly successful." Z-stents were not a panacea, however. They were often too short, meaning stenting over long lengths required multiple stents, each delivered through a separate catheterization. Physicians wanted a stent that could treat longer passageways with only a single catheterization.

The '706 patent – which embodies an improvement of the '568 patent – helped fill this niche, covering a method of connecting several Z-stents together. The application for the '706 patent was filed in 1989 and the '706 patent was issued in 1991. Importantly, the '706 patent uses a series of “eyes” on one end of the stent that interlock with a matching set of eyes on another stent. As Cook states, “the interlocking stent assembly permits and assures a combination of stents that can be deployed at the same time and over longer vessel lengths, to provide a simpler, and less invasive medical procedure.” (Dkt. 107 at 13). Figure 5 of the '706 patent (reproduced below) depicts an example of such a stent assembly.

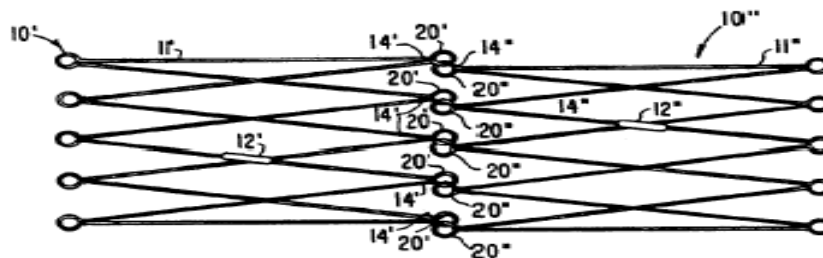


Fig.5

In this lawsuit, Cook contends that its competitor Endologix – a relative newcomer to the market for endovascular technology, at least compared to Cook – is infringing the '706 patent through the sale of its PowerLink stent graft.

1. Claims

In this action, Cook asserts Claims 6 and 12 of the '706 patent against Endologix.¹ Claim 6 of the '706 patent reads as follows:

¹ On April 20, 2010, the PTO issued a reexamination certificate confirming the patentability of Claims 6 and 12 of the '706 patent.

Claim 6:

A method for combining a first and second self-expanding stent to form a stent assembly for insertion into a body passageway comprising the steps of:

forming a first stent from a continuous first length of wire formed into a closed zig-zag configuration having an endless series of straight sections joined at their ends by a plurality of bends;

forming a second stent from a continuous second length of wire formed into a closed zig-zag configuration having an endless series of straight sections joined at their ends by a plurality of bends, the bends at one end defining eyes open at the straight sections of the second stent;

engaging the eyes at the one end of the second stent about bends at one end of the first stent; and closing the eyes at the one end of the second stent.

Claim 12 of the '706 patent reads as follows:

Claim 12:

A stent assembly comprising:

a first wire formed into a closed zig-zag configuration including;

an endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends to form a first stent;

and

a second wire formed into a closed zig-zag configuration including;

a second endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends to form a second stent;

a set of eyes formed at several of said bends at one of said opposite ends;

wherein said first and second stents are resiliently contractable into smaller first shape for conveyance through a body passageway;

wherein said first and second stents are resiliently expandable into a second shape in which the straight sections press against the walls of the body passageway; and

wherein said set of eyes of said second stent are engaged about said first wire at one of said opposite ends of said first wire.

2. *Disputed Terms*

The parties dispute many of the ‘706 patent’s terms for purposes of *Markman* construction. Each disputed term is addressed in turn.

Term 1: “for combining . . .”

Claim Term	Endologix’s Construction	Cook’s Construction
for combining a first and second self-expanding stent to form a stent assembly	for attaching two tubular structures capable of being inserted into and holding open a human body passageway and that spring open when a compressive force is removed, so as to form a pair of connected stents	for combining a first stent that spring expands when a compressive force is removed and a second stent that spring expands when a compressive force is removed to form a stent assembly

This term is found in the preamble of Claim 6. Normally, terms recited in the preamble of a claim are merely “a convenient label for the invention as a whole,” and, therefore, do not limit the scope of the claim. *Storage Technology Corp. v. Cisco Systems, Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003). Where, however, a preamble term is necessary to breathe “life, meaning, and vitality” into the claim, the preamble will be limiting. *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1305 (Fed. Cir. 2005). Both parties ask the Court to construe this term; therefore, the Court will heed their request.

Cook’s proposed construction is limited, primarily asking the Court to construe “self-expanding” to mean that the stent “spring expands when a compressive force is removed.”

Endologix, on the other hand, proposes a more in-depth construction that would construe “combining,” “stent,” “self-expanding,” and “stent assembly.”

As an initial matter, the Court believes that the terms “combining,” “stent,” and “stent assembly” require no construction, since their ordinary meaning is readily understandable. The Federal Circuit has encouraged courts to give a claim term its ordinary meaning when appropriate. *Phillips*, 415 F.3d at 1314 (“In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.”). Moreover, the Court agrees with Cook that “expands” is a more fitting term than “open.” In the Court’s view, “open” is something of a binary concept: either something is open or it’s closed. Expands, by contrast, implies more of a process. In other words, a stent could be in the process of *expanding*, even if it’s not yet fully *open*.

Finally, Endologix’s use of the word “pair” is somewhat misguided, given that “pair” denotes “two,” while Figure 6 of the ‘706 patent shows *three* interlocking stents. (Dkt. 107-5 at 3). Moreover, the ‘706 patent specification makes clear that “[a] number of self-expanding stents can be combined by joining the stents at the eyes.” (Dkt. 107-5 at 6; col. 2, ll. 32-34; emphasis added). This language reinforces that Endologix’s use of “pair” is improper. For these reasons, the Court adopts Cook’s proposed construction.

Term 2: “closed zig-zag . . .”

Claim Term	Endologix’s Construction	Cook’s Construction
wire formed into a closed zig-zag configuration	zig-zag structure with the two ends of the wire joined together	A series of zig-zags traveling in a generally circular path and defining a cylindrical configuration

Claims 6 and 12 state that the wire is “formed into a closed zig-zag configuration.” The term “closed” is at the heart of the parties’ dispute. Endologix argues that “closed” refers to the fact that the two ends of the wire are joined together. Cook, by contrast, argues that “closed” refers to the overall three dimensional configuration of the formed stent.

To bolster its position, Cook notes that the ‘568 patent is incorporated by reference in the specification of the ‘706 patent. Indeed, “[w]hen a document is incorporated by reference into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein.” *Vishay Dale Electronics, Inc. v. Cyntec Co., Ltd.*, 627 F. Supp. 2d 1050, 1058 (D. Neb. 2008) (citation and internal quotations omitted). Cook then highlights that the ‘568 patent’s specification in the preferred embodiment section states that “the stent has generally a circular configuration or a cylindrical configuration when it is in its second expanded shape.” (Dkt. 107-6 at 6; col. 3, ll. 2-4; emphasis added). But, in the Court’s view, “circular” or “cylindrical” would constitute a marked deviation from the plain and ordinary meaning of “closed.” This raises the question: If the drafter meant for “closed” to mean “cylindrical” or “circular,” why not just say it? *See Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997) (“as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must

bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure.”).

Moreover, the ‘706 patent specification in the preferred embodiment section indicates that “closed” refers to the two ends of the wire being joined together, stating that “the percutaneous stent 10 which is formed in a closed zig-zag configuration. The ends of the wire are closed by a sleeve 12 which is welded or tightly squeezed against the ends of the wire to produce a continuous or endless configuration.” (Dkt. 107-5 at 7; col. 3, ll. 60-65; emphasis added). The ‘568 patent specification largely echoes this statement, providing “[t]he wire is closed by a sleeve 11 which is welded or tightly squeezed against the ends of the wire to produce the endless configuration.” (Dkt. 107-6 at 5; col. 2, ll. 52-55; emphasis added) Cook counters that Endologix’s construction reads a limitation from a preferred embodiment into the Claims. However, the Court is not persuaded. The Claim requires a “wire formed into a closed . . . configuration,” and Cook does not identify any way to “close” a wire other than by joining the ends together. The Court is persuaded that “closed” refers to the fact the ends of the wire are joined together. Accordingly, the Court adopts Endologix’s proposed construction, as it aligns with the plain meaning of the claim language and the intrinsic evidence.

Term 3: “endless series . . .”

Claim Term	Endologix’s Construction	Cook’s Construction
having an endless series of straight sections joined at their ends by a plurality of bends	having a repeating pattern of straight sections connected by bends and forming a single ring	the series of straight portions of the generally cylindrical configuration, where adjacent ends of the straight section are joined by a bend.

Claim 6 describes “having an endless series of straight sections joined at their ends by a plurality of bends.” Cook emphasizes that “having an endless series of straight sections” characterizes the overall “configuration,” making for a mechanically efficient way of compressing the stent for purposes of self-expansion. Endologix emphasizes that “endless” means just that – a never-ending or repeating pattern that is caused by the act of “closing” (i.e. joining the two ends of the wire together). Endologix further emphasizes that this concept is supported by the specification of the ‘706 patent, which states: “The ends of the wire are closed by a sleeve 12 which is welded or tightly squeezed against the ends of the wire to produce a continuous or endless configuration. The length 11 of wire is arranged in a number of side-by-side straight sections.” (Dkt. 107-5 at 7; col. 3, ll. 62-67; emphasis added). The Court believes that, generally, Endologix has the stronger argument.

On this point, Cook does not really address the meaning of “endless” in its construction. Along similar lines, the Court believes that Cook’s proposed construction for “closed” and “endless” are essentially identical, meaning that if the Court adopted both of Cook’s constructions, one of these terms would be rendered superfluous. *See Merck & Co. v. Teva Pharms, USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”).

That said, the Court is concerned by the portion of Endologix’s proposed construction involving the formation of “a single ring,” which could imply a two dimensional object. A stent, by contrast, is three dimensional. In the Court’s view, a more accurate description of the resulting structure of the stent – which is what the word “endless” is getting at – is a “configuration that is generally cylindrical upon expanding.” Accordingly, the Court modifies Endologix’s proposed construction and construes “an endless series of straight sections joined at

their ends by a plurality of bends” as “having a repeating pattern of straight sections connected by bends and forming a configuration that is generally cylindrical upon expanding.”

Term 4: “forming . . . from a continuous . . . length of wire”

Claim Term	Endologix’s Construction	Cook’s Construction
forming a [first/second] stent from a continuous [first/second] length of wire	forming a [first/second] stent from a single [first/second] length of wire	forming a [first/second] self-expanding stent from a single [first/second] length of wire

This term is found in Claim 6. Endologix only quarrels with Cook’s inclusion of the phrase “self-expanding.” Given that the stent at issue is unquestionably self-expanding, the Court sees no problem with the inclusion of this phrase. Accordingly, the Court agrees with Cook’s proposed construction.

Term 5: bends at one end defining eyes open

Claim Term	Endologix’s Construction	Cook’s Construction
bends at one end defining eyes open	bends at one end defining sections of wire largely enclosing a space and linked to the ends of the straight sections by cusps or sharp bends	bends at one end defining partial loops

This term is found in Claim 6. The parties dispute the meaning of the term “eyes open.” Significantly, the specification in the preferred embodiment section of the ‘706 patent states:

In one novel aspect of the present invention, the cusps 14 of the stent are formed into a number of eyes 20. In the preferred embodiment, the eyes are formed in the continuous wire 11 and the intersection between adjacent straight sections 13 at the cusps 14 are soldered or welded together to provide a closed loop for the eyes 20.

(Dkt. 107-7 at 7; col. 4, ll. 15-21; emphasis added). Endologix argues that the inclusion of the phrase “the present invention” clarifies that the use of “cusps” is not just one embodiment of the invention, but instead a “fundamental feature” of the invention. (Dkt. 118 at 18). Indeed, “when the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment.” *Chimie v. PPG Industries, Inc.*, 402 F.3d 1371, 1379 (Fed. Cir. 2005) (citation and internal quotations omitted).

Cook, of course, disagrees, contending that this language is merely directed to a preferred embodiment. *See Kara Tech*, 582 F.3d at 1348 (“The claims, not the specification embodiments, define the scope of patent protection.”). In other words, although a preferred embodiment may use cusps, they are not required to make the invention. To bolster this argument, Cook relies heavily on the reexamination proceedings.

In the end, the Court is persuaded by Endologix’s argument, as the language “the present invention” used in the first sentence of the above excerpted paragraph is “strong evidence” as to how the claim language should be read. *See SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1343 (Fed. Cir. 2001) (construing term to include feature of “the present invention”).² Additionally, the second sentence of the above excerpted

² At oral arguments (Dkt. 139 at 74), Cook highlighted *Flexhead Industries, Inc. v. Easyflex, Inc.*, 2008 WL 4813797 (D. Mass. Nov. 3, 2008) for the proposition that the phrase “one aspect of the invention” does not refer to the invention as a *whole*, but merely an embodiment. *Id.* at *6. However, under these circumstances, the Court is not persuaded. In the Court’s view, “aspect” is synonymous with “a feature,” not an “embodiment.”

paragraph reinforces this position, as it begins with the phrase, “In the preferred embodiment. . . .”. This language would be altogether superfluous if the first sentence was already *limited* to a preferred embodiment. Moreover, the Court’s decision is fortified by the fact that Cook never identifies a disclosure or description in the ‘706 specification that does *not* include cusps.

Further, the results of the reexamination proceedings do not compel a contrary ruling. In the reexamination, the examiner found that “the loop or hook . . . of Wiktor are not closed like the eyes in the ‘706 patent and therefore, Wiktor does not teach the step of closing the eyes in claim 6.” (Dkt. 121-5 at 4). However, the examiner did not equate a “partial loop” with an “open eye,” as Cook suggests.

That said, the Court is reticent to adopt Endologix’s entire proposed construction. Specifically, Endologix’s use of the word “space” in the phrase “largely enclosing a *space*” is vague. The Court believes that in lieu of “space,” “loop” better aligns with the claim language. This position is reinforced by the ‘706 patent specification: “In the preferred embodiment, the eyes are formed in the continuous wire 11 and the intersection between adjacent straight sections 13 at the cusps 14 are soldered or welded together to provide a closed loop for the eyes 20.” (Dkt. 107-5 at 7; col. 4, ll. 17-21; emphasis added). For these reasons, the Court construes “bends at one end defining eyes open” as “bends at one end defining sections of wire largely enclosing a loop and linked to the ends of the straight sections by cusps or sharp bends.”

Term 6: Engaging the eyes

Claim Term	Endologix's Construction	Cook's Construction
engaging the eyes at the one end of the second stent about bends at one end of the first stent	then interlocking each open eye at the one end of the second stent with a bend at one end of the first stent	interlocking the eyes at the one end of the second stent with bends at one end of the first stent

The parties generally agree that “engaging” in this Claim 6 term means “interlocking.” So, fortunately, their dispute is limited to the use of the word “then.” Stated differently, does Claim 6 dictate a sequence to the claimed steps? Relying on *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363 (Fed. Cir. 2003), Endologix argues that it does. *See id.* at 1369 (steps can be implicitly construed to require an order “as a matter of logic or grammar”). Relying on that same case, Cook argues that it does not. *See id.* at 1371 (refusing to limit claims to sequence even though preferred embodiment showed a sequence of steps; “[n]owhere, however, is there any statement that this order is important, any disclaimer of any other order of steps, or any other prosecution history indicating a surrender of any other order of steps.”).

The Court sides with Cook. The crux of Endologix’s argument is that the engaging step can only occur after completely forming the stents. However, this position appears to be contradicted by the specification, which contemplates the possibility that engaging can occur prior to the second stent’s completion: “the eyes 20” formed at one end of the stent are interlocked with the eyes 20’ of the first stent 10’. Once the second stent 10” is complete. . . .” (Dkt. 107-5 at 7; col. 4, ll. 40-43; emphasis added). Moreover, it is worth noting that the preamble of Claim 6 uses the phrase “comprising the steps of,” which weighs against requiring a

precise sequential order. *See Ductmate Industries, Inc. v. Famous Supply Corp.*, 55 F. Supp. 2d 777, 784 (N.D. Ohio 1999) (“The Court construes the language *comprising the steps of* . . . to not require a person assembling the ducts to follow the identified steps in exact sequential order.”). In the Court’s view, engaging can still occur while the second stent is still forming; consequently, the Court adopts Cook’s proposed construction.

Term 7: closing the eyes

Claim Term	Endologix’s Construction	Cook’s Construction
closing the eyes at the one end of the second stent	then altering the shape of each open eye to completely enclose a space	forming loops at the end of the second stent

This term, found in Claim 6, is disputed on two grounds. First, Endologix’s proposed construction uses the word “then.” For reasons similar to those explained directly above, however, the Court is not persuaded that this inclusion is appropriate.

Second, the parties revisit a variation of the “loop” versus “enclosed space” debate that was discussed in the construction of the term “eyes open.” Specifically, Cook likens “closing the eyes” to “forming loops.” To bolster this proposed construction, Cook points to the ‘706 patent specification in the preferred embodiment section: “the eyes are formed in the continuous wire 11 and the intersection between adjacent straight sections 13 at the cusps 14 are soldered or welded together to provide a closed loop for the eyes 20.” (Dkt. 107-5 at 7; col. 4, ll. 17-21; emphasis added). However, the Court is not persuaded and agrees with Endologix that “[a]t this stage of the claimed method, the eye is being changed from open to closed, not being “formed” in the first place.” (Dkt. 118 at 21). For this reason, the Court finds that Endologix’s proposed

construction is more appropriate – with two caveats. First, the Court finds that Endologix’s use of “then” is improper. Second, for the reasons set forth above, in the “defining eyes open” term, “space” should be replaced with “loop.” For these reasons, the Court construes “closing the eyes at the one end of the second stent” as “altering the shape of each open eye to completely enclose a loop.”

Term 8: “endless series of . . .”

Claim Term	Endologix’s Construction	Cook’s Construction
endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends	repeating pattern of straight sections connected by bends and forming a single ring wherein all of the bends are located at one or other ends of the ring	the series of straight portions of the generally cylindrical configuration, where adjacent ends of the straight sections are joined by a bend

This term is found in Claim 12 of the ‘706 patent. The Court has already construed a similar term in Claim 6 involving the phrase “endless series of straight sections.” In doing so, the Court adopted a modified version of Endologix’s construction, expressing its discomfort with the phrase “forming a single ring” because it could imply a two dimensional object. In doing so, the Court replaced “forming a single ring” with “forming a configuration that is generally cylindrical upon expanding.” The Court takes the same approach with the present term. *See Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) (“Unless otherwise compelled, when different claims of a patent use the same language, we give that language the same effect in each claim.”).

However, the Court finds the remaining portion of Endologix’s proposed construction confusing. The language “located at one or other ends” implies one out of two, which strikes the

Court as misguided. The Court’s understanding is that bends are located at *both* ends of the straight section. Accordingly, the Court construes “endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends” as “repeating pattern of straight sections connected by bends and forming a configuration that is generally cylindrical upon expanding, where adjacent ends of the straight sections are joined by a bend.”

Term 9: “set of eyes formed at several of said bends . . .”

Claim Term	Endologix’s Construction	Cook’s Construction
set of eyes formed at several of said bends at one of said opposite ends	sections of wire each enclosing a space and linked to the ends of the straight sections by cusps or sharp bends at more than two of the bends at one of the opposite ends of the second stent	a loop is formed at each of at least two bends

This term is found in Claim 12 of the ‘706 patent. It essentially boils down to the meaning of “several.” Specifically, does “several” mean two or more? Or does it mean more than two?

Cook argues that “several” includes two; Endologix argues that it doesn’t. Cook derives its position from the “Summary of the Invention,” which states that “[o]ne object of the invention is to provide a self-expanding stent that permits the combination of several interlocked stents for insertion into a body passageway.” (Dkt. 107-5 at 6-7; col. 2, l. 67 to col. 3, l. 1; emphasis added). And, significantly, the “Description of Drawings” clearly identifies an assembly of *two* interlocked stents as “an embodiment of the present invention.” (Dkt. 107-5 at 3, 7; col. 3, ll. 20-21). When these portions of the patent are viewed in conjunction, Cook argues, the conclusion that “several” can mean two is inescapable. The Court agrees.

Endologix emphasizes that the drafter could've used a clearer term – like “two or more” or “plurality” – in lieu of “several.” Perhaps, but the intrinsic evidence still indicates that “several” can mean two. For this reason, the Court sides with Cook in terms of the meaning of “several.” However, as a matter of consistency in light of the Court’s prior constructions, the Court believes it must use Endologix’s proposed construction, *See Innova/Pure Water*, 381 F.3d at 1119, but with two caveats: (1) replace “more than two” with “two or more”; and (2) replace “space” with “loop.” Accordingly, the Court construes “set of eyes formed at several of said bends at one of said opposite ends” as “sections of wire each enclosing a loop and linked to the ends of the straight sections by cusps or sharp bends at two or more of the bends at one of the opposite ends of the second stent.”

Term 10: resiliently contractable

Claim Term	Endologix’s Construction	Cook’s Construction
resiliently contractable	No construction is necessary	spring-like and capable of contracting

Endologix does not meaningfully dispute Cook’s proposed construction of this term found in Claim 12. Therefore, the Court adopts Cook’s proposed construction.

Term 11: “resiliently expandable into a second shape”

Claim Term	Endologix’s Construction	Cook’s Construction
resiliently expandable into a second shape	No construction is necessary	spring-like and capable of expanding into a second shape

Endologix does not meaningfully dispute Cook’s proposed construction of this term found in Claim 12. Therefore, the Court adopts Cook’s proposed construction.

Term 12: “in which the straight sections press against the walls . . .”

Claim Term	Endologix’s Construction	Cook’s Construction
in which the straight sections press against the walls of the body passageway	in which every straight section of the first and second stents directly engages and applies force to the walls of the body passageway	where the straight sections are capable of pressing against the walls of a body passageway

This term, used in Claim 12, boils down to the word “press.” Specifically, does term require all the straight sections to *actually press* against the walls of the body passageway? Endologix argues “yes,” whereas Cook argues that the straight sections must merely be *capable of pressing* against the walls of the body passageway.

Endologix’s appears to have the stronger hand; its proposed construction is backed by the plain language of the Claim, the summary of the invention, and the background of the invention. *See, e.g.*, Dkt. 107-5 at 6; col., ll. 37-40 (“Once within the body passageway, the stents are resiliently expandable into a larger second shape wherein the straight sections press against the walls of the passageway to maintain it open.”) (emphasis added); *Id.*; col. 1, ll. 30-34 (“the sheath is withdrawn, thereby allowing the stent to expand in the passageway into its expanded shape to hold the passageway open and enlarged . . . [t]hus, the Z-stent provides a self-expanding means for maintaining an open passageway.”) (emphasis added). Moreover, the ‘568 patent specification in the preferred embodiment section confirms that the stents expand to “hug the vessel wall.” (Dkt. 107-6 at 6; col. 3, l. 18).

Cook counters that Claim 12 is an apparatus claim relating to structure and inherent capability, not a method claim. Therefore, according to Cook, the straight sections only need to be *capable* of pressing and need not *actually* press. See *Spine Solutions, Inc. v. Medtronic Sofamor Danek, Inc.*, 2008 WL 4831770, at *8 (W.D. Tenn. July 2, 2008) (“the terms at issue here use active language to describe the *capability* of the apparatuses; they do not claim the activity itself.”) (citation and internal quotations omitted). Moreover, Cook emphasizes that Figure 5 of the ‘706 patent does not show a stent pressing against a wall.

This argument has some appeal, but the Court is not persuaded. The patent drafter obviously knew how to convey *capability*, given his choice of the terms “expandable” and “contractable,” which denote *capability* of expanding or contracting. But the drafter did not say “pressable” or “capable of pressing” or “can be adapted to press against the walls.” Rather, the drafter conveyed that the straight sections *press* against the walls. “Press” is not the same as “capable of pressing” and it was the former that was chosen for Claim 12. Moreover, in *Spine Solutions*, the court acknowledged that “a functional limitation . . . an attempt to define something by what it does, rather than by what it is . . . is not, in and of itself, improper.” *Spine Solution*, 2008 WL 4831770, at *8 (citations and internal quotations omitted). What is more, the Court believes that Cook’s argument relating to Figure 5 is a red herring, given that it just shows the embodiment by itself – it doesn’t show a vessel wall. For these reasons, the Court sides with Endologix’s proposed construction.

Term 13: “said set of eyes of said second stent . . .”

Claim Term	Endologix’s Construction	Cook’s Construction
set of eyes of said second stent are engaged about said first wire at one of said opposite ends	every eye of the second stent encloses a bend at one of the opposite ends of the first stent	the wire at the end of the first stent is disposed through at least two loops of the second stent

This Claim 12 term relates to whether every eye must be engaged. The Court agrees with Endologix’s argument that, without indicating a precise number, the *entire* set of eyes needs to be engaged about the wire to satisfy this claim limitation. This position is reinforced by the Figures depicting the embodiments of the ‘706 patent. Simply stated, all eyes (not just some) are always connected. Moreover, in the Court’s view, Endologix’s proposed construction better aligns with the plain meaning of the claim language. For these reasons, the Court adopts Endologix’s proposed construction.

For the reasons set forth above, the disputed claim terms have the following meanings:

<u>CLAIM TERM</u>	<u>MEANING</u>
for combining a first and second self expanding stent to form a stent assembly	for combining a first stent that spring expands when a compressive force is removed and a second stent that spring expands when a compressive force is removed to form a stent assembly
closed zig-zag configuration	zig-zag structure with the two ends of the wire joined together
having an endless series of straight sections joined at their ends by a plurality of bends	having a repeating pattern of straight sections connected by bends and forming a configuration that is generally cylindrical upon expanding

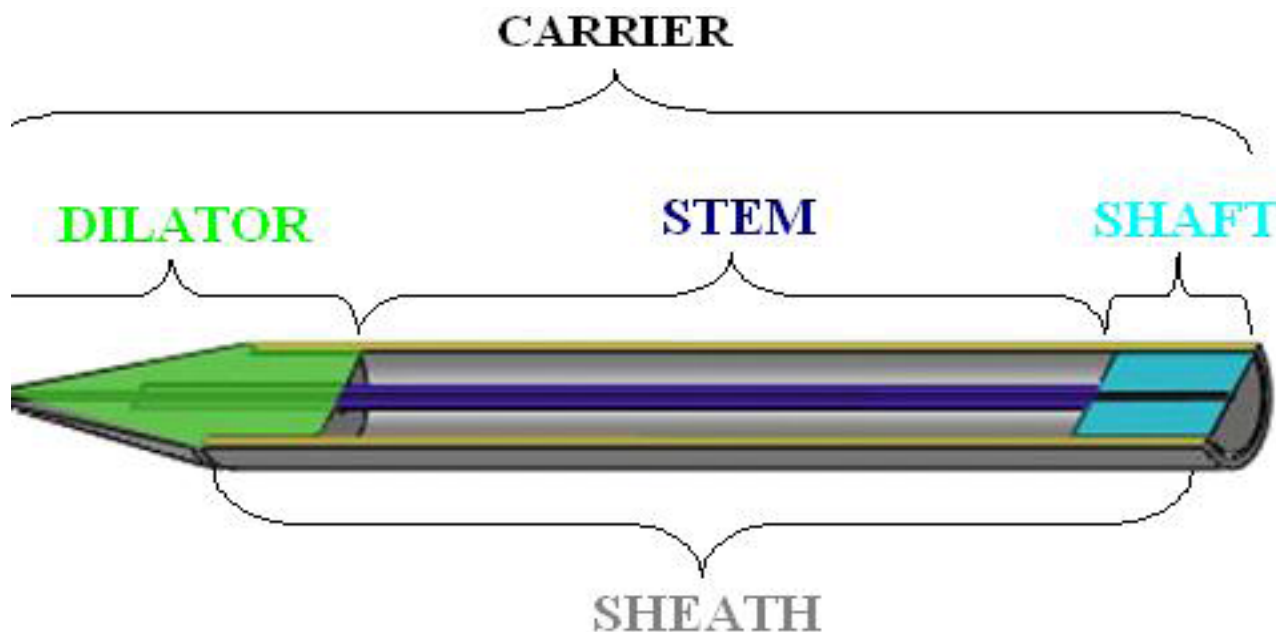
forming a [first/second] stent from a continuous [first/second] length of wire	forming a [first/second] self-expanding stent from a single [first/second] length of wire
bends at one end defining eyes open	bends at one end defining sections of wire largely enclosing a loop and linked to the ends of the straight sections by cusps or sharp bends
engaging the eyes at the one end of the second stent about bends at one end of the first stent	interlocking the eyes at the one end of the second stent with bends at one end of the first stent
closing the eyes at the one end of the second stent	altering the shape of each open eye to completely enclose a loop
endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends	repeating pattern of straight sections connected by bends and forming a configuration that is generally cylindrical upon expanding, where adjacent ends of the straight sections are joined by a bend
set of eyes formed at several of said bends at one of said opposite ends	sections of wire each enclosing a loop and linked to the ends of the straight sections by cusps or sharp bends at two or more of the bends at one of the opposite ends of the second stent
resiliently contractable	spring-like and capable of contracting
resiliently expandable into a second shape	spring-like and capable of expanding into a second shape
in which the straight sections press against the walls of the body passageway	in which every straight section of the first and second stents directly engages and applies force to the walls of the body passageway

said set of eyes of said second stent are engaged about said first wire at one of said opposite ends	every eye of the second stent encloses a bend at one of the opposite ends of the first stent
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B. The ‘777 patent

As mentioned, the ‘777 patent is directed to a delivery device involving the delivery of a self-expanding prosthesis. Prior to the ‘777 patent, delivery systems were ill-suited for AAA repairs. For instance, they were too large to be inserted through remote vessels in a patient’s leg, used sharp and traumatic structures that could damage vessels during a procedure, and were subject to inaccurate positioning. The ‘777 patent helped ameliorate these problems, reducing the risk of vessel damage and allowing for less complicated and more accurate prosthesis placement. The original patent application, for what later became the ‘777 patent, was filed in 1991 and the ‘777 patent was issued in 1998.

Generally, the delivery device contemplated by the ‘777 patent involves a self-expanding prosthesis that is positioned on a carrier, which holds the prosthesis in position during delivery. The carrier is inserted into a tubular introducer sheath. The prosthesis is carried on a region of the carrier called the stem. The sheath is inserted through a small incision in the patient’s femoral artery and snaked through the patient’s arteries to the aorta where the self-expanding prosthesis is released. A three dimensional example of the ‘777 patent is depicted below.



Cook alleges that Endologix is infringing the '777 patent through the sale of its Intuitrak delivery system.

1. *Claims*

Cook asserts Claims 1 and 21-30 of the '777 patent.³ Given the large number of Claims at issue, the Court will not recite them. Instead, the Court will immediately turn to the disputed terms.

2. *Disputed Terms*

Each disputed term in the '777 patent is addressed in turn below.

³ On July 20, 2010, the PTO issued a reexamination certificate, confirming the patentability of the delivery system. In doing so, the PTO confirmed the patentability of amended Claim 1 and over 10 other Claims. Additionally, the PTO confirmed the patentability of the device recited in Claim 11, but, in doing so, required Cook to add that the "delivery system is characterized by absence of a guiding catheter" in light of the prior art.

Term 1: “self expanding prosthesis” (preamble of Claims 1, 21-24, 30)

Claim Term	Endologix’s Construction	Cook’s Construction
self expanding prosthesis	No construction necessary	a graft conduit that spring expands when a compressive force is removed

For the ‘706 patent, the Court has already construed “self expanding” as something that spring expands when a compressive force is removed. That same reasoning applies for this term in the ‘777 patent. The Court must now determine if it is appropriate to construe “prosthesis.” In light of the ‘777 patent’s background and summary sections, Cook argues that the “prosthesis” means “graft conduit.” (Dkt. 108-1 at 21; col. 1, ll. 42-43) (“The prosthetic graft of the invention will provide a resilient conduit . . .”) (emphasis added); *see also* Dkt. 108-1 at 22; col. 3, ll. 49-50 (“[t]he present invention provides a transluminal graft prosthesis that can be safely and precisely positioned”) (emphasis added); *see also SciMed*, 242 F.3d at 1343 (construing term to include feature characterized as “the present invention”)). The Court respectfully disagrees. The phrase “graft conduit” is never actually used in the specification. Moreover, in the Court’s view, the term “prosthesis” needs no special construction. *See Phillips*, 415 F.3d at 1314. For these reasons, the Court construes “self expanding prosthesis” as “a prosthesis that spring expands when a compressive force is removed.”

Term 2: “introducer sheath” (Claims 1, 21-24, 30)

Claim Term	Endologix’s Construction	Cook’s Construction
introducer sheath	a hollow tube extending from outside the body to define a conduit into and through a vessel in the human body	an outermost sheath defining a conduit between a body lumen to be treated and the outside of the body

The parties agree that an “introducer” sheath defines a conduit. Unfortunately, however, that is where the agreement ends. Cook argues that its proposed construction is better because it gives real meaning to the term “introducer,” which must mean a sheath “in direct contact with the vasculature.” (Dkt. 121 at 20). Endologix counters that Cook’s use of the term “outermost” has no basis and that the term “sheath” needs to be construed.

With respect to the need to construe “sheath,” the Court agrees with Endologix. The ’777 patent specification describes the introducer sheath as “tubular in form” (Dkt. 108-1 at 25; col. 10, l. 49) and “a tubular structure (Dkt. 108-1 at 26; col. 11, l. 15). Moreover, the sheath must be a “hollow tube” to receive the “carrier”: “The tubular carrier 21 fits inside the introducer sheath 4.” (Dkt. 108-1 at 25; col. 10, ll. 49-50). Thus, in the Court’s view, construing sheath as a “hollow tube” is appropriate.

Further, the Court agrees with Endologix that the use of the term “outermost” is confusing, as it implies the existence of some “innermost” sheath. Cook claims that Endologix’s proposed construction fails to explain what “introducer” means. However, the Court is not persuaded, as Endologix’s proposed construction states that the sheath “define[s] a conduit into and through a vessel in the human body.” In the Court’s view, this language adequately captures the meaning of the word “introducer.” This position is supported by the ’777 patent

specification, which describes the introducer sheath as “a large conduit between the arterial circulation and the outside of the body.” (Dkt. 108-125; col. 10, ll. 23-24). For these reasons, the Court sides with Endologix’s proposed construction.

Terms 3: “sheath bore of a substantially constant diameter” (Claim 1)

Claim Term	Endologix’s Construction	Cook’s Construction
sheath bore of a substantially constant diameter extending longitudinally therethrough	an internal diameter that varies by no more than manufacturing tolerances throughout the entire length of the introducer sheath	the sheath bore has a substantially constant diameter along its length

Term 4: “uniform sheath bore” (Claims 21-24, 30)

Claim Term	Endologix’s Construction	Cook’s Construction
uniform sheath bore extending longitudinally therethrough	an internal diameter that varies by no more than manufacturing tolerances throughout the entire length of the introducer sheath	the sheath bore has a uniform diameter along its length

These terms are grouped together because they cover similar terrain.⁴ The parties’ proposed constructions differ in two key ways. First, Endologix contends that the term “bore” should be construed to denote the “internal diameter” of the sheath, and, on this point, Cook doesn’t put up much of a fight. Therefore, the Court will construe “bore” as “internal diameter.”

Second, Endologix contends that the terms “substantially constant” and “uniform” should be construed. However, the Court is not persuaded, given the relatively plain meaning of these terms. *See Phillips*, 415 F.3d at 1314. Further, Endologix’s proposed construction – involving

⁴ Although the parties disagree about the meaning of “substantially constant” and “uniform,” they agree that, once construed, those terms essentially mean same thing. (Dkt. 118 at 29).

“manufacturing tolerances” – is unsupported by the intrinsic evidence and would amount to a rather marked deviation from the ordinary meaning of these terms. Therefore, the Court adopts something of a hybrid approach. The disputed terms will be construed as “the sheath has an internal diameter that is substantially constant/uniform along its length.”

Term 5: “central carrier” (Claims 1, 21-24, 30)

Claim Term	Endologix’s Construction	Cook’s Construction
central carrier	a structure within the introducer sheath that carries the prosthesis	a structure carried within the introducer sheath

Both proposed constructions describe the central carrier as “a structure within the introducer sheath.” However, the parties dispute whether the term “central carrier” should be construed to “carr[y] a prosthesis.” Endologix argues that it should, while Cook counters that it would be inappropriate to read “prosthesis” into “central carrier” because many of the claims, such as 21-23, “do not positively recite a self-expanding prosthesis, and such a construction would render the positive recitation of a self-expanding prosthesis superfluous in those claims that do.” (Dkt. 107 at 32).

This argument is well-taken, but the Court respectfully disagrees. The preamble of every asserted claim refers to “a self expanding *prosthesis delivery system*.” (Dkt. 108-2 at 4-5). Moreover, as a practical matter, a “carrier” presumably “carries” something. In its reply brief, Cook conceded that “the central carrier is a structure *for carrying* a prosthesis . . .”. (Dkt. 121 at 21). In sum, Endologix’s position better aligns with the plain language of the claims and the intrinsic evidence.

Term 6: “vascular dilator head region” and “having a fixed shape” (Claims 1, 21-24, 30)

Claim Term	Endologix’s Construction	Cook’s Construction
vascular dilator head region	An end of the central carrier that expands the vessel during the introduction of the sheath into the vessel	an elongate region at an end of the central carrier that does not inflate
having a fixed shape	a shape that cannot change	

For this term, the parties wage battle on two key grounds. First, they dispute the construction of “dilator.” Specifically, Endologix contends that the construction should clarify the dilator’s function. After all, a dilator must “dilate” something. Cook, on the other hand, contends that Endologix’s proposed construction reads a method step – “expands the vessel during the introduction of the sheath into the vessel” – into a purely structural claim. *See, e.g., Baldwin Graphic Systems, Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1344 (Fed. Cir. 2008) (“Courts must generally take care to avoid reading process limitations into an apparatus claim.”).

The Court believes that Endologix has the stronger hand. As the Federal Circuit recently noted, “it is entirely proper to consider the *functions* of an invention in seeking to determine the meaning of particular claim language.” *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, 558 F.3d 1368, 1375-76 (Fed. Cir. 2009) (emphasis added; adding functional language of “for piercing the seal” to the term “spike” was appropriate because it defined the degree to which the spike must be pointed); *see also Funai Elec. Co., Ltd. v. Daewoo Electronics. Corp.*, 616 F.3d 1357, 1366 (Fed. Cir. 2010) (“The use of . . . functional language to construe and explain a claim term is not improper. A description of what a component does may add clarity and

understanding to the meaning and scope of the claim.”). At bottom, the Court believes that construing a term of an apparatus claim using some functional language is appropriate, and does not amount to erroneously conflating a method claim with an apparatus claim. Cook, by contrast, reads “dilator” completely out of the claims. For these reasons, the Court adopts Endologix’s construction of “vascular dilator head region.”

Second, the parties dispute the meaning of “having a fixed shape.” Cook contends that this term was defined during the prosecution history (i.e. the back and forth between the patent attorney and the patent examiner) as “does not inflate.” Indeed, “the record before the [PTO] is often of critical significance in determining the meaning of the claims.” *Vitrionics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Endologix, naturally, balks at Cook’s proposed construction, arguing that it runs contrary to the plain language of the claim. To be sure, common sense suggests that “fixed” and “non-inflatable” are separate and distinct concepts.

The Court agrees with Endologix that the prosecution history does not compel a departure from the plain meaning of “having a fixed shape.” The prosecution history established that the dilator head *both* (1) has “a fixed shape” and (2) “does not employ an inflatable balloon.” But the prosecution history did not unequivocally redefine “fixed shape” to mean the lack of an inflatable balloon.⁵ Although a patent applicant may act as his own lexicographer and deviate from the ordinary meaning of words, he “must clearly express that intent.” *Helmsderfer v. Bobrick Washroom Equipment, Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008). Here, the patentee

⁵ To bolster its position that “fixed shape” means “does not inflate,” Cook highlights the prosecution history statement that “the dilator head region has a fixed shape totally unlike the balloon dilator element 64 of Lazarus . . .”. (Dkt. 109-3 at 3). The Court is not persuaded. Having a fixed shape is indeed “totally unlike” being inflatable, but, of course, this does not mean that “fixed” means “non-inflatable.”

did not manifest such a clear and unmistakable intent. For these reasons, Endologix’s construction of “having a fixed shape” is appropriate.

Term 7: “portion mating with and approximating” (Claims 1, 21-24, 30)

Claim Term	Endologix’s Construction	Cook’s Construction
portion mating with and approximating said [substantially constant diameter of said/uniform] sheath bore	portion of the vascular dilator head region in close intimate contact with and sized to fit the sheath bore so that there is no gap between the outer diameter of the dilator head and the inner diameter of the sheath	a portion of the vascular dilator head region contacts the sheath bore and there is no discernable annular gap between the outer diameter of the dilator head portion and the inner diameter of the introducer sheath

The parties’ dispute boils down to the meaning of “mating with and approximating.” Cook initially argued that the phrase “close intimate contact” is unnecessary prolix. However, Cook later softened its stance at oral arguments, conceding that it did not object to the inclusion of this language, since it was used in arguing for patentability during the reexamination. (Dkt. 139 at 125). Along similar lines, the Court is persuaded that Cook’s inclusion of the phrase “discernable annular gap” is appropriate. This language tracks the definition provided during the reexamination proceedings and the related declaration of Mark A. Farber M.D. (Dkt. 118-18 at 8, 29).

Finally, the Court believes that Endologix’s proposed construction of “approximating” as “sized to fit” is misguided; notably, it stands in stark contrast to the definition of “approximating” provided during the reexamination – “close in size.” That said, Cook appears to read “approximating” out of the claims altogether. For these reasons, the Court construes “portion mating with and approximating said [substantially constant diameter of said/uniform]

sheath bore as “portion of the vascular dilator head region in close intimate contact with and close in size to the sheath bore and there is no discernible annular gap between the outer diameter of the dilator head portion and the inner diameter of the introducer sheath.”

Term 8: “shaft region approximating” (Claims 1, 21-24, 30)

Claim Term	Endologix’s Construction	Cook’s Construction
shaft region approximating said [substantially constant diameter of said/uniform] sheath bore	the end of the central carrier opposite the vascular dilator head region sized to fit the sheath bore	elongate region of the central carrier having an outer diameter that is in close proximity with the inner diameter of the introducer sheath

The parties dispute the meaning of “shaft region approximating” on numerous grounds. First, the parties once again dispute the meaning of “approximating.” Endologix construes “approximating” as “sized to fit,” which the Court rejected directly above. Cook uses the phrase “in close proximity,” which strikes the Court as unfounded. Because the Court is uncomfortable with both approaches, it will embrace the meaning of “approximating” adopted above: That is, “close in size.” Accordingly, the Court finds that, under the circumstances, the relevant term language should be construed as “having an outer diameter that is close in size to the inner diameter of the introducer sheath.” This position is reinforced by the specification of the ‘777 patent: “The internal diameter of the introducer sheath corresponds to the external diameter of the central carrier along two regions.” (Dkt. 108-1 at 28; col. 15, ll. 47-49; emphasis added).

Second, the parties dispute whether the construction should specify the location of the shaft region on the central carrier. Specifically, Endologix proposes that the shaft region necessarily means “the end of the central carrier opposite the vascular dilator head region.” The

Court agrees. The ‘777 specification states that the “stem region [is] positioned between the head and shaft regions” (Dkt. 108-1 at 23; col. 5, ll. 48-49) and, significantly, that “[o]ne region is located caudally [towards patient’s feet] at carrier shaft 218, and the other region is located cranially [towards patient’s head] at carrier head 219. In between these two regions is much narrower carrier stem region 220.” (Dkt. 108-1 at 28; col. 15, ll. 49-52).

In the end, the Court adopts a hybrid of the two proposed constructions, construing “shaft region approximating said [substantially constant diameter of said/uniform] sheath bore” as “the end of the central carrier opposite the vascular dilator head region having an outer diameter that is close in size to the inner diameter of the introducer sheath.”

Term 9: “stem region” (Claims 1, 21-24, 30)

Claim Term	Endologix’s Construction	Cook’s Construction
stem region	a narrower section of the central carrier	an elongate region of the central carrier disposed between the vascular dilator head and shaft regions, having an outer diameter that is less than the diameter of the sheath bore along its length, and the stem region is sized so that a self-expanding prosthesis can be positioned around the stem region with the stem disposed within a bore of the prosthesis
positioned between said head and shaft regions and being smaller than said [substantially constant diameter of said/uniform] [sheath] bore for	no construction needed	
positioning coaxially a self-expanding prosthesis therearound	mounting the self expanding prosthesis on the stem region so that they share the same longitudinal axis	

Each component of this term is addressed in turn. First, the Court will construe “stem region.” Endologix construes it as “a narrower section of the central carrier,” while Cook construes it as “an elongate region of the central carrier.” The Court agrees with Endologix that Cook’s use of “elongate” is not particularly helpful. Moreover, Endologix’s description of the stem region as a “narrower section” is consistent with the ‘777 patent specification, which provides “[t]he narrower segment of the central carrier between carrier head 219 and carrier shaft 218 is carrier stem 220.” (Dkt. 108-1 at 28; col. 16, ll. 19-21). Cook’s own brief concedes that “[t]he stem region is narrower so that a self-expanding prosthesis can be positioned around the stem region and in the sheath bore . . .”. (Dkt. 107 at 35; emphasis added). Accordingly, the Court adopts Endologix’s proposed construction of “stem region.”

Second, the Court agrees with Endologix that the phrase “positioned between said head and shaft regions” need not be construed. Replacing the word “positioned” with “disposed” – as Cook proposes – is not particularly helpful, and the meaning of this phrase is clear.

Third, the parties also dispute whether the term “and being smaller than said [substantially constant diameter of said/uniform] [sheath] bore for” needs to be construed. Given the Court’s construction of “stem region” as a “narrower section,” the Court believes Cook’s proposed language is unnecessary. Accordingly, the Court agrees with Endologix that this term need not be construed.

Fourth, following Cook’s reply brief, the parties essentially agree that “coaxially” means that “the prosthesis and stem share *a common longitudinal axis*.” (Dkt. 121 at 23; emphasis in original). Moreover, the Court agrees with Endologix that Cook’s proposed construction does not explain the inclusion of the requirement that “the stem be disposed within a bore of the prosthesis.” Therefore, in the Court’s view, the only remaining dispute involves the use of the

phrase “can be positioned” (Cook’s construction) versus “mounting” (Endologix’s construction). The Court believes that Cook’s proposal stays true to the claim language, which states “for *positioning*.”

Accordingly, the term “stem region positioned between said head and shaft regions and being smaller than said [substantially constant diameter of said/uniform] [sheath] bore for positioning coaxially a self-expanding prosthesis therearound” as “a narrower section of the central carrier positioned between said head and shaft regions and being smaller than said [substantially constant diameter of said/uniform] [sheath] bore, and the stem region is sized so that a self-expanding prosthesis can be positioned around the stem region so that the prosthesis and the stem share a common longitudinal axis.”

Term 10: “around said stem region”

Endologix does not dispute Cook’s proposed interpretation of this term. Accordingly, the Court construes “around said stem region” as “the self-expanding prosthesis is positioned around the stem region with the stem disposed within a bore of the prosthesis.”

Term 11: “configured to span” (Claims 1, 24)

Claim Term	Endologix’s Construction	Cook’s Construction
graft configured to span an aortic aneurysm	graft configured to engage the walls of the aorta beyond the two ends of the aneurysm	a graft sized so that it can be used to repair an aortic aneurysm

The parties hotly contest this term. Relying on *Flexhead Industries, Inc. v. Easyflex, Inc.*, 2008 WL 4813797 (D. Mass. Nov. 3, 2008), Cook argues that the term “configured to span” merely means that the graft should have a size suitable for aortic aneurysm repair. *See id.* at *7

(construing “configured to receive the fire protection sprinkler head” as “set up in a particular way to receive the fire protection sprinkler head”). But this proposed construction creates more questions than answers: Namely, what is a suitable graft size? In the Court’s view, Cook’s construction altogether ignores the word “span.”

The intrinsic and extrinsic evidence generally support Endologix’s proposed construction. Tellingly, the ‘777 patent specification states that “[t]he prosthetic graft of this invention will provide a resilient conduit, bridging the aneurysm and reducing the risk of rupture . . .”. (Dkt. 108-1 at 21; col. 1, ll. 42-44; emphasis added). Moreover, as Endologix highlights, the common definition of span is “to extend across.”

Cook maintains that Endologix’s use of the word “engage” is improper. However, the Court respectfully disagrees. Figure 15 of the ‘777 patent “shows a graft implanted in the aorta on either side of an aneurysm.” (Dkt. 108-1 at 23; col. 6, ll. 48-49) (emphasis added). Moreover, the ‘777 patent specification describes the need “to provide a secure arterial wall for the attachment of the proximal . . . end of the graft . . .”. (Dkt. 108-1 at 27; col. 13, ll. 40-41) (emphasis added). Given this intrinsic evidence, the Court believes that Endologix’s use of “engage” is appropriate. That said, the Court agrees with Cook that “an aortic aneurysm” – rather than “the aortic aneurysm” – stays true to the claim language. Accordingly, the Court construes, “graft configured to span an aortic aneurysm” as “graft configured to engage the walls of an aorta beyond the two ends of an aneurysm.”

Term 12: spring assembly (Claims 1, 24-29)

Endologix has adopted Cook’s proposed construction of this term. Therefore the Court will construe “spring assembl[y/ies] as “an assembly that spring expands when a compressive force is removed.

Term 13: “continuous wire” (Claims 1, 29)

Claim Term	Endologix’s Construction	Cook’s Construction
a continuous wire	a single wire with joined ends	made from a single piece of wire having a series of zig-zags
in the shape of a zig-zag with multiple elbows	no construction necessary	

The parties dispute this term on two grounds. First, does the wire always have joined ends? The plain meaning of “continuous” suggests “yes.” It is, after all, difficult to conceive how one could make a wire “continuous” without joining its ends. Cook’s proposed construction – which essentially just replaces “continuous” with “single” – ignores the ordinary meaning of “continuous.” The ‘777 specification reinforces this position, providing that “[t]he two ends of the piece of bent wire are permanently attached end-to-end so as to form a circular structure.” (Dkt. 108-1 at 24; col. 8, ll. 12-13; emphasis added). Cook counters that Endologix is merely importing a limitation from an example into the Claims. Tellingly, however, Cook never really explains why “continuous” should mean “single.” Therefore, the Court construes “a continuous wire” as “a single wire with joined ends.”

Second, the parties dispute whether “in the shape of a zig-zag with multiple elbows” needs to be construed. The Court believes that Cook’s construction helps clarify the meaning of this language, and Endologix does not meaningfully disagree. Accordingly, the Court construes “a continuous wire in the shape of a zig-zag with multiple elbows” as “a single wire with joined ends having a series of zig-zags.”

Term 14: “aperture longitudinal member” (Claim 1, 27-29)

Thankfully, the parties now agree on these constructions. Therefore, the Court construes: (1) “first assembly comprising an aperture” as “the first spring assembly comprises a structure defining an aperture”; (2) “second assembly comprising a longitudinal member slidably disposed through said aperture” as “the second spring assembly comprises an elongate structure that extends through the aperture of the first spring assembly, and is slidably connected to the first spring assembly via the aperture”; and (3) “portion with a dimension that is larger than said aperture to prevent disengagement of said first and second spring assemblies” as “a portion of the longitudinal member has a dimension that is larger than the aperture to prevent the larger-dimension portion from passing through the aperture.”

Term 15: “seal” (Claims 1, 21)

Claim Term	Endologix’s Construction	Cook’s Construction
seal disposed at a proximal end of said introducer sheath	a seal between the introducer sheath and the central carrier, located on the open end of the introducer sheath closest to the surgeon	a seal disposed at a downstream end of the introducer sheath

The parties’ dispute centers on the word “proximal” (i.e. the location of the seal). Although the parties do not dispute what the proximal end of the sheath is, they dispute the best construction of that word. Cook’s proposed construction simply replaces “proximal” with “downstream.” Indeed, the ‘777 patent specification makes clear that downstream is synonymous with proximal. (*See, e.g.*, Dkt. 108-1 at 23; col. 6, ll. 42-43) (“FIG. 13 is a longitudinal cross-sectional view of the proximal (downstream) end of the introducer sheath”) (emphasis added). Endologix’s more detailed proposed construction is flawed, as, in the Court’s

view, it attempts to read preferred embodiments and non-limiting prosecution history into the claim language. In the end, the Court believes that Cook’s proposed construction best aligns with both the claim language and the intrinsic evidence.

Term 16: absence of a guiding catheter (Claims 1, 23)

Claim Term	Endologix’s Construction	Cook’s Construction
is characterized by the absence of a guiding catheter	does not have a hollow tube for guiding devices through a vessel in the human body	the delivery system can be introduced into the body lumen from the outside of the body without having to guide it to the treatment site through a catheter

This phrase was added to the ‘777 patent as part of the reexamination proceedings. Specifically, the patent examiner stated that the references that Endologix submitted to provoke the reexamination proceedings, among others, “fail[] to teach a delivery system that does not require a guiding catheter as claimed nor would it be obvious to include such a feature...”. (Dkt. 107 at 41). Essentially, the parties’ dispute boils down to whether: (1) the delivery system is *capable of* being used without a guiding catheter (essentially, Cook’s proposed construction); or (2) the delivery system simply *does not have* a guiding catheter (Endologix’s construction). Stated differently, Cook’s proposed construction implies permissiveness: That the delivery system still can be used *with* a guiding catheter, even though it doesn’t *require* one.

To bolster its argument against permissiveness, Endologix relies on *Union Carbide Chems. & Plastics Technology Corp. v. Shell Oil Co.*, 308 F.3d 1167 (Fed. Cir. 2002) for the proposition that “characterized by” means that the delivery system is distinguished from others by this essential characteristic. *Id.* at 1177. *Union Carbide* is not directly on-point, though. In

that case, the Federal Circuit ultimately construed the phrase “characterizable by” to mean “capable of being described by.” *Id.* However, in doing so, the court acknowledged the difference between the plain meaning of “characterizable” and the plain meaning of “characterized.” Indeed, the plain meaning of “characterized by” is “to describe the essential character or quality of . . . to be a distinguishing characteristic of.” *Id.* (citations omitted). Obviously, the distinction between *characterized by* and *characterizable by* is significant; it amounts to the difference between *always having a characteristic* versus merely being *capable of having* a characteristic.

Tellingly, here, the patentee chose “characterized by.” Thus, rather than merely being capable of having “the absence of a guiding catheter,” the delivery device is *defined* by “the absence of a guiding catheter” – i.e. it *never* makes use of a guiding catheter. For this reason, the Court sides with Endologix’s proposed construction.

Moreover, this position is reinforced by the prosecution history, in which Cook went to great lengths to distinguish its delivery system from Garza. Specifically, Mark Farber M.D.’s declaration states that “Claim 25 requires that the delivery system has an introducer sheath, a central carrier, but no guiding catheter . . . Garza clearly has a guiding catheter 78.⁶ In fact, the guiding catheter is described as an integral component of Garza’s delivery system...”. (Dkt. 118-18 at 36) (emphasis added).

That said, the Court does not adopt Endologix’s entire proposed construction, as it sees no reason to construe “catheter,” given its plain meaning. Moreover, the intrinsic evidence does not support Endologix’s proposed construction of “hollow tube.” For these reasons, the Court

⁶ Claim 25 in the reexamination proceeding issued as Claim 23 of the ‘777 Reexamination Certificate.

construes “is characterized by the absence of a guiding catheter” as “does not have a catheter for guiding devices through a vessel in the human body.”

Miscellaneous

The parties have apparently resolved many of their other claim term disputes, including: lip (Claim 22); twist prevention double lumen catheter (Claim 31); cross femoral guide (Claim 31); catheter attached to a caudal end of said contralateral graft limb (Claim 32); and guidewire (Claim 33). Therefore, the Court need not construe these terms.

For the reasons set forth above, the disputed claim terms in the ‘777 patent have the following meanings:

<u>CLAIM TERM</u>	<u>MEANING</u>
self expanding prosthesis	a prosthesis that spring expands when a compressive force is removed
introducer sheath	a hollow tube extending from outside the body to define a conduit into and through a vessel in the human body
sheath bore of a substantially constant diameter extending longitudinally therethrough	the sheath has an internal diameter that is substantially constant along its length
uniform sheath bore extending longitudinally therethrough	the sheath has an internal diameter that is uniform along its length
central carrier	a structure within the introducer sheath that carries the prosthesis
vascular dilator head region having a fixed shape	an end of the central carrier that expands the vessel during the introduction of the sheath into the vessel having a shape that cannot change

portion mating with and approximating said [substantially constant diameter of said/uniform] sheath bore	portion of the vascular dilator head region in close intimate contact with and close in size to the sheath bore and there is no discernible annular gap between the outer diameter of the dilator head portion and the inner diameter of the introducer sheath
shaft region approximating said [substantially constant diameter of said/uniform] sheath bore	the end of the central carrier opposite the vascular dilator head region having an outer diameter that is close in size to the inner diameter of the introducer sheath
stem region	a narrower section of the central carrier
positioned between said head and shaft regions and being smaller than said [substantially constant diameter of said/uniform] [sheath] bore for	No construction needed
Positioning coaxially a self-expanding prosthesis therearound	and the stem region is sized so that a self-expanding prosthesis can be positioned around the stem region so that the prosthesis and the stem share a common longitudinal axis
around said stem region	the self-expanding prosthesis is positioned around the stem region with the stem disposed within a bore of the prosthesis
configured to span	graft configured to engage the walls of an aorta beyond the two ends of an aneurysm
spring assembl[y/ies]	an assembly that spring expands when a compressive force is removed
a continuous wire in the shape of a zig-zag with multiple elbows	a single wire with joined ends having a series of zig-zags
first assembly comprising an aperture	the first spring assembly comprises a structure defining an aperture

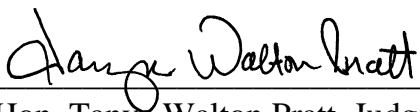
second assembly comprising a longitudinal member slidably disposed through said aperture	the second spring assembly comprises an elongate structure that extends through the aperture of the first spring assembly, and is slidably connected to the first spring assembly via the aperture
portion with a dimension that is larger than said aperture to prevent disengagement of said first and second spring assemblies	a portion of the longitudinal member has a dimension that is larger than the aperture to prevent the larger-dimension portion from passing through the aperture
seal disposed at a proximal end of said introducer sheath	a seal disposed at a downstream end of the introducer sheath
is characterized by the absence of a guiding catheter	does not have a catheter for guiding devices through a vessel in the human body

CONCLUSION

For the reasons set forth above, the disputed claim terms have the meaning set out in this order.

SO ORDERED.

Date: 08/16/2011


 Hon. Tanya Walton Pratt, Judge
 United States District Court
 Southern District of Indiana

Distribution attached.

Distribution to:

Daniel K. Burke
HOOVER HULL LLP
dburke@hooverhull.com,fgipson@hooverhull.com

Joseph S. Cianfrani
KNOBBE MARTENS OLSON & BEAR, LLP
joseph.cianfrani@kmob.com

Kelly J. Eberspecher
BRINKS HOFER GILSON & LIONE
keberspecher@brinkshofer.com

John David Evered
KNOBBE MARTENS OLSON & BEAR, LLP.
2jde@kmob.com,jennifer.ratwani@kmob.com

Andrew W. Hull
HOOVER HULL LLP
awhull@hooverhull.com,fgipson@hooverhull.com

Bradley G. Lane
BRINKS HOFER GILSON & LIONE
blane@brinkshofer.com,federalcourts@brinkshofer.com

Danielle Anne Phillip
BRINKS HOFER GILSON & LIONE
dphillip@brinkshofer.com,danielle.a.phillip@gmail.com

John B. Sganga , Jr
KNOBBE MARTENS OLSON & BEAR, LLP.
2jbs@kmob.com

Joshua J. Stowell
KNOBBE MARTENS OLSON & BEAR, LLP.
2jys@kmob.com